United States District Court
District of Massachusetts

Carol Lewis,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 15-13530-NMG**
	)	
Alex Azar, Secretary of the United States Department of Health and Human Services,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM & ORDER

GORTON, J.

Here we have an appeal of a decision by the Secretary of Health and Human Services ("the Secretary" or "defendant") denying Medicare coverage for a subcutaneous continuous glucose monitor ("CGM") used by Carol Lewis ("Lewis" or "plaintiff").

Pending before the Court are plaintiff's motions to alter the judgment and for a hearing on that motion. For the reasons that follow, plaintiff's motion to alter the judgment will be allowed and her motion for hearing will be denied as moot. Summary judgment will be entered in favor of plaintiff.

III. Background

Carol Lewis has had Type 1 diabetes for over 30 years. Consequently, she suffers from hypoglycemia and hyperglycemic unawareness, which means that she cannot determine whether she

is experiencing a glucose "high" or "low". To combat the malady, Lewis's doctor prescribed her a continuous glucose monitor ("CGM"). That device, which is implanted under a patient's skin, computes blood glucose level and transmits that information to a receiver which, in turn, alerts the user of her glucose level. CGM devices also provide information as to the trends of a user's glucose level, allowing a patient and physician to devise a long-term glucose management plan.

In March, 2013, Lewis submitted five claims to the National Health Insurance Corporation ("NHIC") for a total of $2,842 for her use of a Medtronic brand CGM device in June 2011 and March, June, September and November 2012. Those claims were denied and plaintiff filed an appeal of the denials with the Medicare Appeals Council ("the Council") on March 24, 2014. The Council also denied her claims. It held that the subject equipment did not "serve a medical purpose" as required by agency regulation, 42 C.F.R. § 414.202, and that the CGM was merely precautionary. Accordingly, it found, the CGM was not covered under the Durable Medical Equipment ("DME") Medicare benefit. Plaintiff petitioned this Court for judicial review in October, 2015. In her complaint, plaintiff states that she

> seeks an order reversing these coverage denials and instructing the Secretary to pay the claims at issue.

In January, 2017, plaintiff filed a motion for summary judgment, arguing that the Secretary's decision that the CGM

device was not covered by Medicare was arbitrary and capricious and not supported by substantial evidence. In due course, defendant filed a motion to affirm the secretary's decision and a reply to plaintiff's opposition thereto. In defendant's reply, the government for the first time argued that plaintiff's claim was moot because plaintiff had switched from using her Medtronic brand CGM device (which was not covered) to a Dexcom brand CGM device (which was covered).

In August, 2017, this Court treated that reply as "defendant's motion to dismiss plaintiff's claims for lack of subject matter jurisdiction" and allowed the motion, holding that the plaintiff's claims were moot. The Court stated

> Because plaintiff is not using the subject CGM equipment, she lacks a legal interest in the outcome of the case and, therefore, her claims will be dismissed as moot.

IV. Motion to alter the judgment

A motion for reconsideration is an "extraordinary remedy" granted only when the movant demonstrates that the court committed a "manifest error of law" or that newly discovered evidence not previously available has come to light. Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006) (quoting Charles Alan Wright et al., Federal Practice and Procedure § 2810.1 (2d ed. 1995)). Here, plaintiff argues that the Court erred in denying her action as moot.

Mootness is a constitutional issue that a court should ordinarily resolve before reaching the merits. ACLU of Mass. v. U.S. Conference of Catholic Bishops, 705 F.3d 44, 52 (1st Cir. 2013). The mootness doctrine ensures that claims are to be justiciable throughout litigation not only when a claim is initially filed. Id. The First Circuit Court of Appeals has identified the following instances of cases becoming moot:

1) when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome;

2) when the court cannot give any effectual relief to the potentially prevailing party; and

3) if events have transpired to render a court opinion merely advisory.

KG Urban Enters., LLC v. Patrick, 969 F. Supp. 2d 52, 56 (D. Mass. 2013) (citing Catholic Bishops, 705 F.3d at 52-53).

Upon careful reconsideration, none of those instances is present in this case. The plaintiff seeks reimbursement for funds she spent on her Medtronic CGM device in 2011 and 2012. She states that the Secretary erred in his designation of the claims from 2011 and 2012 because the Medtronic CGM device should have been deemed a covered device. Whether or not Lewis continued using the device after those dates is irrelevant to whether she is entitled to reimbursement for those claims under the Medicare Act. Indeed, her complaint states that she

> seeks an order reversing these [i.e. the 2011 and 2012 payments] denials and instructing the Secretary to pay the claims at issue.

As a consequence, her claim for reimbursement is not moot because she retains a legally cognizable interest in those funds. See Knox v. Serv. Employees Int'l Union, Local 1000, 567 U.S. 298, 307-08 (2012).

Accordingly, plaintiff's motion to alter the judgment will be allowed.

V. Standard of Review

"Administration of the Medicare program is governed by title XVIII of the [Social Security] Act." Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22619, 22620 (Apr. 27, 1999). Under the Medicare program, benefits available to eligible beneficiaries are called covered services. Medicare is a defined benefit program which means that the services covered are

> broadly defined in the Act[] in . . . benefit categories. . . . Specific health care services must fit into one of these benefit categories to be eligible for coverage under Medicare.

Id.

To be covered, the item or service must also be "reasonable and necessary" and not otherwise excluded from coverage. See 42 U.S.C. § 1395y(a)(1).

The Act provides coverage for "medical and other health services," 42 U.S.C. § 1395k(a), which is defined to include "durable medical equipment" ("DME"), 42 U.S.C. § 1395x(s)(6). Section 1861(n) of the Act contains a non-exhaustive list of certain items that are automatically classified as durable medical equipment. See § 1395x(n). Included within that list are blood glucose monitors for individuals with diabetes.

An item not included within the list may still qualify as durable medical equipment if it satisfies the following regulatory definition:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
>
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> (3) Is primarily and customarily used to serve a medical purpose.
>
> (4) Generally is not useful to an individual in the absence of an illness or injury.
>
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

Judicial review of Administration decisions under the Social Security Act is governed by 42 U.S.C. § 405(g). Walker-Butler v. Berryhill, 857 F.3d 1, 3 (1st Cir. 2017). Federal courts "have the power to enter . . . a judgment affirming,

modifying or reversing the decision of the Commissioner." 42 U.S.C. § 405(g).

The Court shall affirm the final decision if it is supported by substantial evidence and the correct legal standard is used. Seavey v. Barnhart, 276 F.3d 1, 9 (1st Cir. 2001). The agency's findings of fact, "if supported by substantial evidence, shall be conclusive." Seavey, 276 F.3d at 10 (quoting 42 U.S.C. § 405(g)). The Court reviews issues of law de novo. Id. at 9. Mixed questions of law and fact fall on a sliding scale for which "the more fact-dominated the question, the more likely it is that the trier's resolution of it will be accepted" unless that decision is clearly erroneous. In re Extradition of Howard, 996 F.2d 1320, 1328 (1st Cir. 1993) (internal citations omitted).

V. Analysis

Lewis maintains that the Secretary's decision is wrong on both the law and the facts. She contends that the conclusion that CGM does not perform a medical purpose, and therefore does not qualify as DME, is not supported by substantial evidence and is contrary to the administrative record.

The Secretary responds that the Council correctly determined that CGM serves a precautionary, not medical, purpose

because CGM cannot be relied upon independently to make a glucose determination.

To qualify as a DME, a device must be "primarily and customarily used to serve a medical purpose." See 42 C.F.R. § 414.202. The Food and Drug Administration, the National Institutes of Health and multiple professional medical societies such as the American Diabetes Association and the American Medical Association deem CGM primarily and customarily to serve a medical purpose as a medical device. The Secretary makes no mention of the opinions of those societies in his decision. But see Medicare Benefit Policy Manual, Chap. 15, § 110.1(B)(1) (providing that the determination of whether a specific item of equipment is medical in nature is to include the advice of medical societies and specialists in the field). His decision is not supported by substantial evidence.

"Precautionary" is defined in neither the Act nor its regulations. The only example provided for precautionary-type equipment is a preset portable oxygen unit. See id. at § 110.1(B)(2). A CGM, in contrast to a "back-up" oxygen tank, is used as a primary monitoring device. It is the primary method of glucose monitoring for persons with hypoglycemic unawareness. Although the Council maintained that a CGM serves a duplicative function to a fingerstick, it failed to recognize

that CGM devices also provide trend information and overnight monitoring that fingersticks cannot provide.

The fact that fingersticks may be used to confirm the results of a CGM does not deprive a CGM of its "primarily medical" character. First, Medicare frequently covers confirmatory testing. Second, the FDA recognizes that a CGM may be a diabetic's sole means of monitoring glucose levels. The Secretary's assertion that a device loses its medical nature if it is used in conjunction with another medical device is contrary to law. See Finigan v. Burwell, 189 F. Supp. 3d 201, 207 n. 6 (D. Mass. 2016) (rejecting Secretary's argument that CGMs are precautionary because they may be used in conjunction with other monitoring equipment).

The Council's decision that CGM devices are not primarily and customarily used to serve a medical purpose constituted legal error and was not supported by substantial evidence. The petitioner's motion for summary judgment will therefore be allowed. See Tangney v. Burwell, 186 F. Supp. 3d 45, 57 (D. Mass. 2016).

ORDER

For the foregoing reasons, plaintiff's motion to alter or amend the judgment (Docket No. 60), entered on August 22, 2017 with respect to plaintiff's motion for summary judgment (Docket No. 48) is **ALLOWED** and judgment is entered in favor of

plaintiff. Plaintiff's motion for hearing (Docket No. 72) is **DENIED AS MOOT**.

So ordered.

/s/ Nathaniel M. Gorton_____
Nathaniel M. Gorton
United States District Judge

Dated April 5, 2018